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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,092	10/13/2005	Naoki Kimura	TOYA115.015APC	9129

20995 7590 12/21/2007

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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
12/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,092	KIMURA ET AL.	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-13* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is written in reply to applicant's correspondence filed October 3, 2007. Claims 1, 3-5 and 12 were amended and claim 6 was cancelled. New claim 13 was added. Applicant's amendment requiring immobilization of organic compound on the core particles necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

2. Claims 1-5 and 7-13 are pending in this application.

3. Claims 1-5, 7-11 and 13 are under prosecution.

Amendments to Claims

4. Amendments to the claims 1, 3-5 and 12 have been reviewed and entered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 6-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al (USPGPUB NO. 2001/0055762 published Dec. 27, 2001).

Regarding claim 1, Suzuki et al teaches a carrier for immobilizing a biologically active substance that includes base material, i.e., core particle (paragraph 0024) and a

compound having a carbodiimide group, i.e., an organic compound bound to the surface of the base material via a covalent bond (paragraph 0024) and further teaches that a biologically active substance is bonded to the carrier via carbodiimide group, thus immobilizing biologically active substance on to the carrier (paragraph 0024).

Suzuki et al also teaches that carbodiimide polymer contains 5-30 carbodiimide groups (paragraph 0082) and the carbodiimide group is hydrophilic as defined in the instant specification (See instant specification, paragraphs 0032-0033) thus meeting the limitation of organic compound having two or more hydrophilic groups. The base material with organic compound having hydrophilic groups bound to the base material with bonded biological substance is the base particle of the instant claim.

Suzuki et al further teaches the chemical bond is covalent bond (paragraph 0024) and further teaches that the base material and the biologically active substance are bonded by a reaction with carbodiimide functional group (paragraphs 0083-0084).

Regarding claim 4, Suzuki et al teaches that the base material is a bead (paragraph 0071) and the biological substance is bonded on its surface (paragraph 0024). The bead taught by Suzuki et al meets the limitation of base particle of "substantially spherical shape".

Regarding claims 7 and 11, Suzuki et al teaches that the organic compound is polycarbodiimide represented by the general formula: Ax--(R--X)n--R—Ay (paragraph 0083) wherein Ax and Ay are carbodiimide groups which are hydrophilic segment having functional group that exhibits hydrophilicity as defined in the instant specification (See instant specification, Paragraph 0032-0033) and further teaches that

polycarbodiimide has 5-30 carbodiimide groups (paragraph 0082) thus teaching n is an integer of 5-30 that is in the range of 2-80 (paragraph 0083).

Regarding claim 8, Suzuki et al teaches that the biologically active substance is nucleic acids, proteins, antibodies and antigens (paragraphs 0106-0108).

Regarding claim 9, Suzuki et al teaches that the base particle device for detecting nucleic acids and proteins that is, a second biologically active substance contained in a sample by using a specific bond of the biologically active substance and the second biologically active substance in the sample (paragraphs 0113-0119).

Regarding claim 10, Suzuki et al teaches the biologically active substance is an antibiotic that can be configured for its intended use as an agent for therapeutic treatment of a disease (paragraph 0107).

Regarding claim 13, Suzuki et al also teaches that polycarbodiimide, i.e., organic compound has 5-30 carbodiimide groups (paragraph 0082) and the carbodiimide group is hydrophilic as defined in the instant specification (See instant specification, paragraphs 0032-0033) and further teaches that the biologically active substance is immobilized on the polycarbodiimide bonded carrier in water (paragraph 0111) thus teaching organic compound has water solubility.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al (USPGPUB NO. 2001/0055762 published Dec. 27, 2001) and in view of Sutton et al (USPN 5,955,108 issued September 21, 1999).

Claims 2 and 3 are dependent from claim 1. Teachings of Suzuki et al regarding claim 1 are described previously in this office action.

Regarding claims 2 and 3, Suzuki et al do not teach that the base particles have a diameter range and are monodispersed in an aqueous medium. However, base particles having a diameter range and monodispersed in an aqueous medium were known at the time of the claimed invention was made as taught by Sutton et al.

Regarding claim 2, Sutton et al teaches microparticles conjugated with biological substance with EDCI, a carbodimide compound to generate microcapsules and further teaches that microcapsules are monodispersed in an aqueous medium (column 5, line

21). Sutton et al also teaches the microcapsules are hydrophilic and are biocompatible carrier system and have a prolonged circulatory life time and have potential use for detoxification in extracorporeal system (column 5, lines 41-52).

It would have been prima facia obvious to one having the ordinary skill in the art at the time the invention was made to include the biocompatible microcapsule of Sutton et al in the base particle of Suzuki et with the expected benefit of having microcapsules that are hydrophilic and biocompatible having a prolonged circulatory life time and havinge potential use for detoxification in extracorporeal system as taught by Sutton et al (column 5, lines 41-52), thus expanding the utilities of base particles of Suzuki et al.

Regarding claim 3, Sutton et al teaches that the microcapsule particle has an average particle diameter of 3 to 3.8 micrometer that is within the range of 0.1 to 100 micrometer (column 11, line 24) and further teaches that microcapsules are biocompatible (column 5, line 43) and diameter of below 4 micrometer are for intravenous administration and diameter of 8 to 30 microns are for intra-arterial administration (column 5, lines 1-3).

It would have been prima facia obvious to one having the ordinary skill in the art at the time the invention was made to include the biocompatible microcapsule of particular diameter range of Sutton et al in the base particle of Suzuki et with the expected benefit of having microcapsules of diameter below 4 micrometer for intravenous administration and diameter of 8 to 30 microns for intra-arterial

administration as taught by Sutton et al (column 5, lines 1-3) thus expanding the utilities of base particles of Suzuki et al.

10. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al (USPGPUB NO. 2001/0055762 published Dec. 27, 2001) and in view of Sutton et al (USPN 5,955,108 issued September 21, 1999).

Claim 5 is dependent from claim 4, which is dependent from claim 1. Teachings of Suzuki et al regarding claims 1 and 4 are described previously in this office action.

Regarding claim 5, Suzuki et al in view of Sutton et al teaches the particle size range as a ratio of the interquartile range to the mean diameter (Sutton et al column 5, lines 4-6) but do not teach CVb or CVc ratio. However the ratio of standard deviation of particles was known at the time of the claimed invention was made as taught by Camli et al, who teaches the CV ratio in percentage as the standard deviation to number of particles with diameter of D multiplied by 100 (pg. 417, Column 2, paragraph 1). Camli et al also teaches that CV ratio is very important to identify the narrow range of size distributions (pg. 419, Column 1).

It would have been prima facia obvious to one having the ordinary skill in the art at the time the invention was made to modify the measurement of base particle of Suzuki et al in view of Sutton et al to include the CV ratio measurement of Camli et al with the expected benefit of to identifying the narrow range of size distributions of the particle as taught by Camli et al (pg. 419, column 1) thus providing better quality control

tool for selecting the needed size range of base particle of Suzuki et al in view of Sutton et al.

Response to Remarks from the applicants

Claim objections

11. Objection to the claim 5 in the previous office action is withdrawn in view of applicant's correction of the defect.

Rejections under 35 U.S.C. § 112 Second paragraph

12. All rejections set forth in the previous office action have been withdrawn in view of amendments to the claims.

Rejections under 35 U.S.C. § 102(b)

13. Applicant's arguments with respect to claims 1 and 4-11 as being anticipated by Takenishi et al have been considered but are moot in view of the new grounds of rejection necessitated by amendments to the claims.

Applicant's arguments with respect to claims 1-6 and 8-10 as being anticipated by Sutton et al have been considered but are moot in view of the new grounds of rejection necessitated by amendments to the claims.

Co-Pending Applications of Assignee

14. A list of Co-pending applications of Assignee provided by the Applicant has been reviewed.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat, Ph. D.

Examiner

Art Unit 1634